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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/633,145 | 08/04/2000 | Chinnappa Kodira | CL000747 | 3253 |

7590 08/05/2003

Celera Genomics Corp.
Attn: Robert A. Millman, Patent Director
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| EXAMINER | |
|---|---|
| WEGERT, SANDRA L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | 23 |

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/633,145 | KODIRA ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Wegert | 1647 | |

*-- The MAILING DATE of this communication appears on th cover sheet with the correspondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *4,8,9,13 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9,13 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *19 April 2002* is: a)☐ approved b)☒ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

***Status of Application, Amendments, and/or Claims***

The Request for Reconsideration, filed 16 may 2003 (Paper No. 22) has been entered. Claim 13 was withdrawn by the examiner in Paper 11. Claims 4, 8, 9, and 24-30 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office action.

### *Maintained Objections and/or Rejections*

***35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.***

Claims 4, 8, 9, and 24-30 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 2-9 of the previous Office Action (Paper No. 20, 16 December 2002). Claims 4, 8, 9, and 24-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (Paper No. 20, 16 December 2002), one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to a nucleotide that encodes a protein that possesses approximately 100% homology to a known and well-characterized tyramine receptor, *Tar1* (Bunzow, et al 2001, Mol. Pharmacol., 60: 1181-1188; Bunzow, et al, 2003, Accession No.

NM_138327). The *Tar1* receptor has been studied extensively, and has a unique and specific pharmacological and physiological profile establishing it among the "trace-amine" receptors that respond to tyramine or phenethylamine (Bunzow, et al, 2001, see Figure 2A). As suggested by Bunzow, et al, such receptors are partly responsible for the severe parasympathetic stimulation seen after ergot poisoning.

As discussed in the previous Office Action (p. 3), no well-established utility exists for newly isolated complex biological molecules. The specification does not discuss evidence nor disclose experiments that impart *any* function for the polypeptide encoded by the claimed nucleotides in the context of the cell or organism. The instant Specification suggests that the receptor encoded by the claimed polynucleotides is a member of the *aminergic* G-protein-coupled receptor family (Specification, page 2, first paragraph and page 4, first paragraph) which represents:

**"a large group of GPCRs that share a common evolutionary ancestor and which are present in both vertebrate (deuterostome), and invertebrate (protosome) lineages. This family of GPCRs includes, but is not limited to the 5-HT-like, the dopamine-like, the acetylcholine-like, the adrenaline-like and the melatonin-like GPCRs."** (Specification, page 4, lines 3-7).

The specification does not teach the skilled artisan how to use the receptor encoded by the claimed polynucleotide for any unique or specific purpose. Furthermore, the Specification, *as originally filed*, does not anticipate or even suggest that the disclosed receptor functions as a tyramine receptor like that disclosed and studied by Bunzow, et al (2001, Mol. Pharmacol., 60: 1181-1188). For example, there is no disclosure of specific ligands for the receptor, or of the anticipated changes in receptor-mediated processes in transfected cells, or the probable

phenotypes of "knock-in" or "knock-out" organisms, or of a specific disease caused by an overactivity or underactivity of the receptor.

Applicants argue (page 2; 16 May 2003, Paper No. 22) that the polypeptide disclosed in the instant Specification "has statistically significant homology to serotonin receptors and dopamine receptors in the aminergic receptor domains." The examiner agrees that the disclosed receptor as originally filed could be considered a G protein-coupled receptor. However, this is a large class of receptors, the members of which have many functions within organisms (Ji, et al, 1998, J. Biol. Chem., 273(28): 17299-17302), as discussed in a previous office action (Paper 11, 19 December 2001). However, no information is given in the Specification that would suggest that the disclosed polypeptide of SEQ ID NO: 2 is the *Tar1* G-protein-coupled receptor (Bunzow, et al, 2001) that responds to tyramine or phenethylamine and has a specific function within an organism.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to determine the function of the protein encoded by SEQ ID NO: 1 or 3, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the unpredictability of predicting the function of new proteins based on structure, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

## New Rejections/Objections

***Sequence Rules***

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, especially 1.821, part (c), because each disclosure of a sequence embraced by the definitions set forth in the rules must be accompanied by the required reference to a unique sequence identifier (i.e., SEQ ID NO:). This occurs in Figs. 1, 2 and 3, for example. This rejection was first made in Paper 11 (19 December 2001). Applicant subsequently submitted new figures, purportedly to correct the Sequence errors in Figures 1, 2 and 3 (Paper 13, 24 April, 2002). However, the newly-submitted Figures contain Sequences that do not match the current Sequence Listing (compare the attached Sequence listing with the newly-submitted Figure 2).

Appropriate correction is required. Please submit either: New copies of original Figs 1, 2 and 3 with SEQ ID NO's appropriately inserted, or new copies of Figs 1, 2 and 3 containing line-numbering so that entry of amendments can be more easily facilitated. Submitting the original figures with new SEQ ID NO's will not constitute New Matter, since the figures were present in the Application as originally filed.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
7/28/03

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER